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Vice President, Portfolio Development and Review Grants Working Group Recommendations TRAN April 19, 2022





## **Mission Statement**



#### **OUR MISSION**

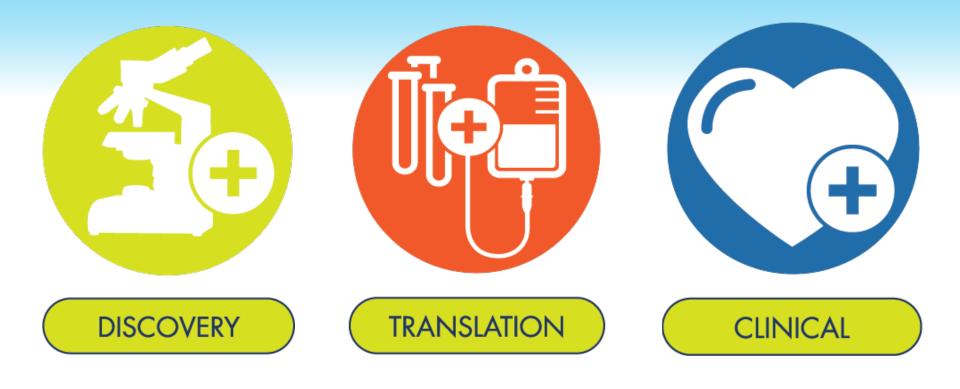
Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world





# **Recurring Programs**





New Idea



Single Product Candidate



Pre-IND or Equivalent



Approved Therapy



# CIRM Translation Program



#### TRAN1 **Therapeutic**

30 months \$4M (Cell/Biologic) \$2M (Drug)

#### TRAN2 Diagnostic

24 months \$1.2M

#### TRAN3 Medical Device

24 months \$2M

#### **TRAN4** Tool

24 months \$1M



## **Translation Program**



Disease modifying activity with candidate

#### Proof of concept with prototype



TRAN1
Therapeutic

30 months \$4M (Cell/Biologic) \$2M (Drug)



TRAN2
Diagnostic

24 months \$1.2M



TRAN3 Medical Device

24 months \$2M



TRAN4 Tool

24 months \$1M

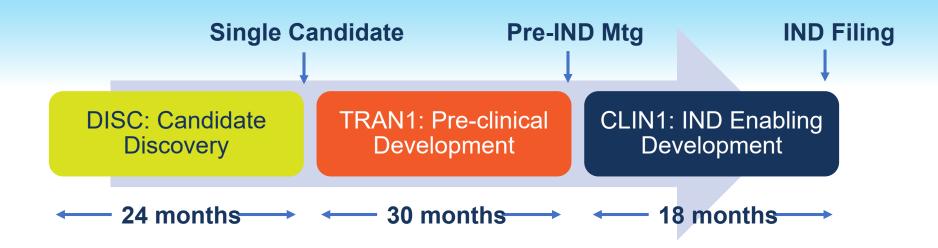


Design transfer to manufacturer

Completed Pre-IND or other Pre-Sub meeting with FDA







#### Expected **outcomes** of TRAN1 applications:

- Pre-IND meeting conducted and formal meeting minutes forwarded to CIRM
- Pivotal IND-enabling preclinical studies protocols drafted
- GMP-compliant Master Cell Bank and Working Cell Bank established
- Clinical indication defined and draft clinical protocol synopsis developed





- Does the project hold the necessary significance and potential for impact? (i.e., what value does it offer; is it worth doing?)
- 2. Is the rationale sound? (i.e., does it make sense?)
- 3. Is the project well planned and designed?
- 4. Is the project feasible? (i.e., can they do it?)
- 5. Does the project address the needs of underserved communities?





#### Score of "85-100"

Recommended for funding, if funds are available

#### Score of "1-84"

Not recommended for funding

Applications are scored by all scientific members of the GWG with no conflict.

The **median** of all individual GWG scores determines final score.





### **GWG** Recommendations



	Number of Apps	Total Applicant Request	Funds Available
Recommended for funding Score 85-100	4	\$18,124,698	\$41,898,065
Not recommended for funding Score 1-84	7		

For each award, the final award amount shall not exceed the amount approved by the ICOC Application Review Subcommittee and may be reduced contingent on CIRM's assessment of allowable costs and activities.

No applications qualified for a minority report.

